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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1408]

International Conference on Harmonisation; Draft Guidance on Principles for Clinical Evaluation of New Antihypertensive Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E12A Principles for Clinical Evaluation of New Antihypertensive Drugs.'' The draft guidance, prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), was designated an ICH principle document. The draft guidance is intended to provide general principles for the clinical evaluation of new antihypertensive drugs. It describes the core principles accepted in the three ICH regions for the evaluation of new antihypertensive drugs, including assessments of efficacy and safety and choice of study population.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics

Evaluation and Research (CBER), 1401 Rockville Pike, Rockville MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert Temple, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug and biological product development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation

of docu...tation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

To facilitate the process of making ICH guidances available to the public, the agency is changing its procedures for publishing ICH guidances. Beginning April 2000, we will follow the same procedures we follow with other agency guidances. Rather than including the text of ICH guidances in the **Federal Register**, we will publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). The draft guidance will be left in the original ICH format. The final guidance will be reformatted to conform to GGP style before publication.

In March 2000, the ICH Steering Committee agreed that a draft guidance entitled ''E12A Principles for Clinical Evaluation of New Antihypertensive Drugs'' should be made available for public comment. The draft guidance, which is the product of the Efficacy Expert Working Group of the ICH, was designated an ICH principle document. Because requirements of the three ICH regions differ in some specifics, this ICH principle document will not be subject to the usual ICH step procedures leading to a fully harmonized document. Comments about this draft will be forwarded to the three regulatory parties for consideration.

In accordance with FDA's good guidance practices (GGP's)(62 FR 8961, February 27, 1997), this document is being called a guidance, rather than a principle document.

The draft guidance is intended to provide general principles for the clinical evaluation of new antihypertensive drugs. It describes core principles that are accepted in the three ICH regions for the evaluation of antihypertensives, including assessments of efficacy and safety and choice

of study population. The draft guidance is meant to be used together with other ICH clinical guidances.

This draft guidance represents the agency's current thinking on the clinical evaluation of new antihypertensive drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the

heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/2/00
August 2, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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